

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S, and)	
ANTON MAYR,)	
)	
Plaintiffs,)	
)	C.A. No. 05-614 (SLR)
v.)	
)	
ACAMBIS INC. and)	
ACAMBIS PLC,)	
)	
Defendants.)	

**DEFENDANTS' ANSWER TO PLAINTIFFS'
FIRST AMENDED COMPLAINT**

Defendants Acambis Inc. and Acambis, plc (collectively "Defendants" or "Acambis"), hereby answer and otherwise respond to the First Amended Complaint of Bavarian Nordic A/S ("BN") and Professor Anton Mayr (collectively "Plaintiffs") as follows:

FIRST DEFENSE – FED. R. CIV. P. 8(b)

NATURE OF CASE

1. Defendants deny that they have committed any acts of unfair competition, conversion, or misappropriation of trade secrets in violation of the laws of the United States or the State of Delaware. Defendants further deny that Plaintiffs are entitled to any relief on any of the claims set forth in the Amended Complaint. Defendants affirmatively aver that BN's trade secrets claim is not currently pending in this case because it was dismissed by the Court in its Memorandum Order on August 21, 2006.

JURISDICTION

2. Defendants admit that this action is between parties whose citizenship is diverse and that Plaintiffs seek relief in excess of \$75,000. Defendants further admit that Plaintiffs cite the Lanham Act as providing federal question subject matter jurisdiction under 28 U.S.C. § 1338. Defendants deny the remaining allegations set forth in Paragraph 2 of the Amended Complaint insofar as they constitute legal conclusions to which no response is required.

3. Defendants admit that this Court has personal jurisdiction in this matter and that venue lies in this District. Defendants deny the remaining allegations set forth in Paragraph 3 of the Amended Complaint insofar as they constitute legal conclusions to which no response is required.

THE PARTIES

4. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 4 of the Amended Complaint and therefore deny those allegations. Defendants further deny that BN owns any proprietary information or material upon which a claim may be based against Acambis.

5. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 5 of the Amended Complaint and therefore deny those allegations. Defendants further deny that Professor Anton Mayr is the owner of any material upon which a claim may be based against Acambis.

6. Defendants deny that the acts complained of in the Amended Complaint occurred in Delaware. Defendants admit the remaining allegations set forth in Paragraph 6 of the Amended Complaint.

7. Defendants deny that the acts complained of in the Amended Complaint occurred in Delaware. Defendants admit the remaining allegations set forth in Paragraph 7 of the Amended Complaint.

8. Defendants deny the allegations set forth in Paragraph 8 of the Amended Complaint insofar as they constitute legal conclusions to which no response is required. Defendants admit that Acambis Inc. and Acambis plc share research personnel and jointly market vaccine product to the U.S. Government.

FACTUAL BACKGROUND

9. Defendants admit that the allegations set forth in Paragraph 9 of the Amended Complaint are generally correct.

10. Defendants admit that the allegations set forth in Paragraph 10 of the Amended Complaint are generally correct, and affirmatively aver that other smallpox vaccines – including some that are derived from the Dryvax® virus strain and some that are derived from other virus strains – are currently being evaluated.

11. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 11 of the Amended Complaint and therefore deny those allegations.

12. Defendants deny that BN developed a new generation of smallpox vaccines. Defendants affirmatively aver that MVA-based smallpox vaccines have been in use since the 1970s. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 12 of the Amended Complaint and therefore deny those allegations.

13. Defendants deny that MVA-BN cannot replicate inside human cells. Defendants affirmatively aver that MVA-BN has been shown to replicate to some degree in human cells just like all other strains of MVA. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 13 of the Amended Complaint and therefore deny those allegations.

14. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 14 of the Amended Complaint and therefore deny those allegations.

15. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 15 of the Amended Complaint and therefore deny those allegations. Defendants affirmatively aver that in an action filed contemporaneously with this suit before the U.S. International Trade Commission (“ITC action”), BN has accused Defendants of infringing the patents identified in Paragraph 15. In that forum, Defendants challenged the alleged infringement, validity, and enforceability of the patents. On September 6, 2006, the administrative law judge in the ITC proceeding invalidated each and every patent claim that BN alleges that Acambis infringed. BN has represented in this forum that “none of [its] claims in this lawsuit allege or depend upon patent infringement.” BN has further confirmed that “[p]atent claims and defenses are squarely before the ITC, not here.”

16. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 16 of the Amended Complaint and therefore deny those allegations.

17. Defendants admit the allegations set forth in Paragraph 17 of the Amended Complaint.

18. Defendants deny providing ACAM2000 vaccine under the contract awarded in September 2000. Defendants admit the remainder of the allegations set forth in Paragraph 18 of the Amended Complaint. Defendants affirmatively aver that Acambis received a competitively awarded contract from the U.S. Government in September 2000 to research, develop and license a smallpox vaccine derived from the same vaccine strain as Dryvax® (ACAM1000), and that Acambis received a second competitively awarded U.S. Government contract in November 2001 to research, develop, manufacture and license a smallpox vaccine derived from the same vaccine strain as Dryvax® (ACAM2000).

19. Defendants deny the allegations set forth in Paragraph 19 of the Amended Complaint.

20. Defendants admit that Baxter Healthcare SA (“Baxter”) is Acambis Inc.’s subcontract manufacturer of MVA3000 under two prime contracts between the U.S. Government and Acambis Inc. Defendants further admit that Baxter manufactures or intends to manufacture MVA3000 in Europe, at least in substantial part, for delivery in the United States to the U.S. Government. Defendants also affirmatively aver that their only current MVA3000 “customer” in the United States is the U.S. Government, and admit that they have delivered approximately 500,000 doses of MVA3000 to the U.S. Government. Defendants deny the remainder of the allegations in Paragraph 20 of the Amended Complaint.

21. Defendants deny the allegations set forth in Paragraph 21 of the Amended Complaint. Defendants further deny the allegations set forth in Paragraph 21 of the Amended Complaint insofar as they constitute legal conclusions to which no response is required.

22. Defendants deny the allegations set forth in Paragraph 22 of the Amended Complaint. Defendants further deny the allegations set forth in Paragraph 22 of the Amended Complaint insofar as they constitute legal conclusions to which no response is required. Defendants affirmatively aver that the NIH provided the strain at issue to Acambis and that before doing so the NIH made its own determination that Plaintiffs did not possess any ownership rights thereto.

23. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 23 of the Amended Complaint and therefore deny those allegations. Defendants admit that Prof. Mayr created MVA.

24. Defendants deny the allegations set forth in Paragraph 24 of the Amended Complaint. Defendants deny that BN holds an exclusive license to research and commercialize all MVA strains. Defendants deny that BN acquired ownership of all MVA strains. Defendants deny that Plaintiffs' have any rights to the MVA strain used by Acambis. Defendants further deny the allegations set forth in Paragraph 24 of the Amended Complaint insofar as they constitute legal conclusions to which no response is required.

25. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 25 of the Amended Complaint and therefore deny those allegations.

26. Defendants admit that a strain of MVA was deposited with the ECACC. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 26 of the Amended Complaint and therefore deny those allegations.

27. Defendants admit that Dr. Moss obtained MVA-575. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 27 of the Amended Complaint and therefore deny those allegations.

28. Defendants admit that Dr. Moss obtained MVA-572. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 28 of the Amended Complaint and therefore deny those allegations.

29. Defendants deny that there were any restrictions on the use of the MVA strains obtained by Dr. Moss. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 29 of the Amended Complaint and therefore deny those allegations. Defendants affirmatively aver that they were not under any restriction with respect to the use of any MVA strain provided to them by the NIH.

30. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 30 of the Amended Complaint and therefore deny those allegations. Defendants affirmatively aver that they were not under any restriction with respect to the use of any MVA strain provided to them by the NIH.

31. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 31 of the Amended Complaint and therefore

deny those allegations. Defendants affirmatively aver that BN never plaque purified any MVA and especially MVA-572.

32. Defendants admit that Acambis plc entered into an agreement entitled “Secrecy Agreement” with BN in February 2002, but deny the remaining allegations set forth in Paragraph 32.

33. Defendants admit that personnel from Acambis and BN met at Acambis’ offices in Cambridge, Massachusetts, on June 12, 2002, and that Thomas Monath, the Chief Scientific Officer of Acambis Inc., attended some or all of the meeting. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 33 and therefore deny those allegations. Defendants further deny that BN disclosed any non-public, confidential or proprietary information during that meeting, or that Defendants misappropriated any such information for their own commercial benefit.

34. Defendants admit that sometime in 2002, BN delivered a draft outline of a proposal for a potential collaboration between BN and Acambis. Defendants deny the remaining allegations set forth in Paragraph 34.

35. Defendants admit that the allegations set forth in Paragraph 35 of the Amended Complaint are generally correct, but affirmatively aver that the U.S. Government expressed an interest in stockpiling smallpox vaccines prior to September 11, 2001, and acted on that interest by competitively awarding Acambis a smallpox vaccine contract in September 2000 (ACAM1000).

36. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 36 of the Amended Complaint and therefore

deny those allegations. Defendants admit that personnel from Acambis and BN met at Acambis' offices in Cambridge, Massachusetts, on June 12, 2002, but affirmatively aver that neither NIAID nor NIH were present at, nor participated in, that meeting.

37. Defendants admit that NIAID NIH released the First RFP in September 2002 outlining the requirements for an attenuated form of the smallpox vaccine virus, including dosage. Defendants deny the remaining allegations in Paragraph 37 of the Amended Complaint. Defendants affirmatively aver that the First RFP invited any offeror to enter into "collaborative opportunities" with the NIH and that such opportunities were specifically not part of the RFP. These "opportunities" included "the availability of master seed stock of MVA from NIAID."

38. Defendants deny that there were any restrictions on the use of the MVA strains obtained by Dr. Moss. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 38 of the Amended Complaint and therefore deny those allegations. Defendants affirmatively aver that they were not under any restrictions with respect to the use of any MVA strain provided to them by the NIH.

39. Defendants admit the allegations set forth in Paragraph 39 of the Amended Complaint.

40. Defendants admit receiving MVA, which was plaque purified from 572.FHE-22.02.1974 by Dr. Bernard Moss, from NIH NIAID. Defendants deny the remainder of the allegations in Paragraph 40. Defendants affirmatively aver being in possession of MVA strains prior to the contract award in February 2003.

41. Defendants are without knowledge sufficient to form a belief as to the truth of the allegations set forth in Paragraph 41 of the Amended Complaint and therefore deny those allegations.

42. Defendants admit that they initiated human clinical trials of MVA3000 under a U.S. Investigational New Drug (IND) application in 2004 and announced results of those trials in April 2005. Defendants deny the remaining allegations set forth in Paragraph 42 of the Amended Complaint.

43. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 43 of the Amended Complaint and therefore deny those allegations.

44. Defendants deny the allegations set forth in Paragraph 44 of the Amended Complaint.

COUNT I – TORTIOUS CONVERSION

45. Defendants incorporate Paragraphs 1 through 44 above by reference.

46. Defendants deny the allegations set forth in Paragraph 46 of the Amended Complaint.

47. Defendants deny the allegations set forth in Paragraph 47 of the Amended Complaint.

48. Defendants deny the allegations set forth in Paragraph 48 of the Amended Complaint.

49. Defendants deny the allegations set forth in Paragraph 49 of the Amended Complaint.

50. Defendants deny the allegations set forth in Paragraph 50 of the Amended Complaint.

51. Defendants deny the allegations set forth in Paragraph 51 of the Amended Complaint.

52. Defendants deny the allegations set forth in Paragraph 52 of the Amended Complaint.

COUNT II – MISAPPROPRIATION OF TRADE SECRETS

53. Count II is not a pending claim in this case because it was dismissed by the Court in its Memorandum Order on August 21, 2006. Likewise, any of the allegations in paragraphs 1 through 52 that relate solely to BN's trade secrets claim have also been dismissed. Defendants understand that Plaintiffs included Count II, and the preceding allegations on which it is based, in the Amended Complaint "purely to forestall any argument that plaintiffs have voluntarily dropped that claim, and not to derogate the effect of the August 21 Order." Letter from counsel for Plaintiffs to counsel for Defendants (Aug. 23, 2006). Accordingly, Defendants are responding to the allegations of Count II, and the allegations of paragraphs 1 through 52 insofar as they relate to BN's trade secret claim, with that understanding and subject to Plaintiffs representation that the Court's Order applies equally to Plaintiffs' Amended Complaint. Defendants incorporate their responses to Paragraphs 1 through 52 above by reference.

54. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such

information for their own commercial benefit. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 54 of the Amended Complaint and therefore deny those allegations. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 54 and the allegations set forth therein have been dismissed.

55. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 55 of the Amended Complaint and therefore deny those allegations. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 55 and the allegations set forth therein have been dismissed.

56. Defendants deny that BN disclosed any non-public, confidential or proprietary information to Defendants, or that Defendants misappropriated any such information for their own commercial benefit. Defendants are without knowledge sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 56 of the Amended Complaint and therefore deny those allegations. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 56 and the allegations set forth therein have been dismissed.

57. Defendants deny the allegations set forth in Paragraph 57 of the Amended Complaint. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 57 and the allegations set forth therein have been dismissed.

58. Defendants admit that, as of June 12, 2002, they were aware that BN was seeking to develop a MVA-based smallpox vaccine. Defendants deny the remaining allegations set forth in Paragraph 58 of the Amended Complaint. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 58 and the allegations set forth therein have been dismissed.

59. Defendants deny the allegations set forth in Paragraph 59 of the Amended Complaint. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 59 and the allegations set forth therein have been dismissed.

60. Defendants deny the allegations set forth in Paragraph 60 of the Amended Complaint. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 60 and the allegations set forth therein have been dismissed.

61. Defendants deny the allegations set forth in Paragraph 61 of the Amended Complaint. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 61 and the allegations set forth therein have been dismissed.

62. Defendants deny the allegations set forth in Paragraph 62 of the Amended Complaint. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 62 and the allegations set forth therein have been dismissed.

63. Defendants deny the allegations set forth in Paragraph 63 of the Amended Complaint. Defendants affirmatively aver that, as explained in paragraph 53, paragraph 63 and the allegations set forth therein have been dismissed.

COUNT III – UNFAIR TRADE PRACTICES

64. Defendants incorporate Paragraphs 1 through 63 above by reference. To the extent that Count III is based on trade secret misappropriation, it has been dismissed,

as explained in paragraph 53. Furthermore, 6 Del. C. § 2007(a), Delaware's Trade Secret Act displaces unfair trade claims based on trade secret misappropriations

65. Defendants deny the allegations set forth in Paragraph 65 of the Amended Complaint.

66. Defendants deny the allegations set forth in Paragraph 66 of the Amended Complaint.

67. Defendants deny the allegations set forth in Paragraph 67 of the Amended Complaint.

68. Defendants deny the allegations set forth in Paragraph 68 of the Amended Complaint.

COUNT IV – LANHAM ACT UNFAIR COMPETITION

69. Defendants incorporate Paragraphs 1 through 68 above by reference. To the extent that Count IV is based on trade secret misappropriation, it has been dismissed as explained in paragraph 53.

70. Defendants deny the allegations set forth in Paragraph 70 of the Amended Complaint.

71. Defendants deny the allegations set forth in Paragraph 71 of the Amended Complaint.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any relief in this matter. Defendants request attorneys' fees pursuant to 15 U.S.C. § 1117 and Del. C. Ann. 6 § 2533, and any other applicable provisions.

SECOND DEFENSE – FED. R. CIV. P. 8(c)¹

a. Plaintiffs bring this action with unclean hands by using the processes of this Court for improper business purposes.

b. Plaintiffs' claims are barred by the doctrine of laches, estoppel, and/or waiver insofar as Plaintiffs' were aware of the alleged basis for the claims made in the Amended Complaint at least as early as February 2003 – prior to the U.S. Government's subsequent MVA-related RFPs – but took no action. Such delay has caused and/or will cause prejudice and injury to Defendants and third parties.

c. Some or all of Plaintiffs' claims may be subject to binding arbitration.

d. Plaintiffs' claims are barred insofar as BN and/or its agents provided the property and/or information at issue to the U.S. Government without restriction.

e. Plaintiffs' claims are barred insofar as Plaintiffs and/or their agents did not have the authority to restrict the U.S. Government's use and provision of the property and/or information at issue.

f. Plaintiffs' claims are barred insofar as Plaintiffs and/or their agents did not have rights in the property and/or information at issue.

g. Plaintiff's claims are barred by the statute of limitations.

THIRD DEFENSE – FED. R. CIV. P. 12(b)(6)

Plaintiffs fail to state any claim upon which relief can be granted under any theory.

¹ Defendants have omitted their inequitable conduct defense because it was dismissed by the Court pursuant to its Order dated August, 10, 2006. Defendants have not asserted their patent invalidity and unenforceability, Walker Process and sham litigation counter-claims due to the Court's Memorandum Order dated August 21, 2006. However, Defendants do not intend to waive their rights in any regard in connection with these defenses and claims.

FOURTH DEFENSE – FED. R. CIV. P. 12(b)(7)

Plaintiffs’ claims must be dismissed for failure to join the U.S. Government as an indispensable party insofar as the U.S. Government owns or will own the vaccines sought by Plaintiffs’ request for injunctive relief. That request includes a demand for the “return of all MVA virus and its progeny in the possession of [Defendants] and/or [their] suppliers.” Prayer for Relief at ¶ D. The U.S. Government is also an indispensable party insofar as it is alleged in the Amended Complaint (*see, e.g.*, ¶ 39) to be Defendants’ supplier of the MVA strain used to develop and manufacture Defendants’ MVA3000 vaccine. The proper forum for pursuing relief against the U.S. Government is the U.S. Court of Federal Claims pursuant to 19 U.S.C. § 1337(l) and/or the Tucker Act, 28 U.S.C. § 1491 *et seq.*

SEVENTH DEFENSE

Defendants reserve the right to present additional affirmative defenses and/or responses and/or counterclaims as such matters are revealed during the course of the litigation.

DEMAND FOR A JURY TRIAL

Defendants respectfully demand a trial by jury on all issues, claims, and causes of action appropriately tried to a jury.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Mary B. Graham

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September 7, 2006
536154

CERTIFICATE OF SERVICE

I hereby certify that on September 7, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

John W. Shaw, Esquire
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Wilmington, DE 19801

Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on September 7, 2006 upon the following individuals in the manner indicated:

BY HAND

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